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REMARKS

Applicants discovered that exendins, exendin agonists, exendin analogs, and exendin derivatives are useful in beneficially regulating gastrointestinal motility. The pending claims are directed toward these beneficial methods.

All of the outstanding rejections of these claims are at least partly based on the Examiner's concern about the scope of the terms exendin, exendin agonist, exendin analog, and exendin derivative. These concerns are addressed below and Applicants submit that the scope of the claims embodying the recited terms is readily determinable by one of skill in the art.

In any event, certain exendins and exendin agonist analogs are recited in particular pending dependent claims. For example, claims 35-36 recite methods using exendin-3 or exendin-4. Claims 41-42 recite methods using the exendin agonists of SEQ ID NO. 38 and SEQ ID NO. 39. Irrespective of the claims from which they depend, these claims are, thus, allowable as there is no dispute that they are both clear and enabled. Notification of the same is respectfully requested.

The 35 U.S.C. §112, Second Paragraph, Rejection

Claims 31-51 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. This rejection is respectfully traversed.

Initially, Applicants note that the Examiner's conclusion regarding the definiteness of Applicants' claims is contrary to the law. Although not mentioned in the Office Action, the legal standard for determining whether a claim is definite is well-established. If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, 35 U.S.C. §112 demands no more. See Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1385, 231 USPQ 81, 94-95 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987). Also see Miles Lab., Inc. v. Shandon Inc., 997 F.2d 870, 875, 27 USPQ2d 1123, 1126 (Fed. Cir. 1993), *cert. denied*, 114 S. Ct. 943 (1994). As Judge Rich, co-author of the 1952 Patent Act, stated in In re Borkowski, 422 F.2d 904, 909, 164 USPQ 642, 645-46 (CCPA 1970) (footnotes omitted, first emphasis in original; second emphasis added):

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The first sentence of the second paragraph of §112 is essentially a requirement for *precision and definiteness* of claim language. If the scope of subject matter embraced by a claim is clear, and if the applicant has not otherwise indicated that he intends the claim to be of a different scope, then the claim does particularly point out and distinctly claim the subject matter which applicant regards as his invention.

Accord, In re Hyatt, 218 USPQ 195, 197 (Fed. Cir. 1983).

An Examiner's desire for precise definitions must give way to what those skilled in the art understand to be the scope of the claims. See W.L. Gore & Assoc., Inc. v. Garlock, Inc., 721 F.2d 1540, 1556-58, 220 USPQ 303, 315-16 (Fed. Cir. 1983). As stated in In re Hallman, 210 USPQ 609, 611 (CCPA 1981), "It is well settled that there is nothing intrinsically wrong in defining something by what it does rather than by what it is. In re Echerd, 471 F.2d 632, 176 USPQ 321 (CCPA 1973); In re Swinehart, 58 CCPA 1027, 439 F.2d 210, 169 USPQ 226 (1971); In re Fuetterer, 50 CCPA 1453, 319 F.2d 259, 138 USPQ 217 (1963)." The primary focus is whether the claims reasonably apprise those of skill in the art of their scope. The claims do just that in the present case.

The Term "Exendin"

Notwithstanding the above legal principles, the Examiner alleges that claims 31-34 are indefinite on the assertion that what is encompassed by the term "exendin" is not clear. Applicants respectfully disagree with the Examiner's assertion. The term "exendin" is clear and well understood.

Exemplary exendins known as of the filing date of the present application are clearly identified in the specification. As set forth in the scientific literature, including by peptide sequence (e.g., see page 2, lines 1-4, of the specification), and as those in the art are well aware, exemplary exendins are exendin-3 and exendin-4 (i.e., the peptides found in Heloderma horridum and Heloderma suspectum). Applicants found these peptides to be useful in beneficially regulating gastrointestinal motility by reducing gastric motility or delaying gastric emptying.¹

¹ Exendin (9-39), contrary to the Examiner's assertion, is an exendin antagonist. It is not an exendin according to the present invention. Page 3, line 19, to page 4, line 16, of the specification, for example, describes

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Withdrawal of the rejection based on the use of the term "exendin" is respectfully requested as one of skill in the art is clearly able to determine what is encompassed by the term exendin and, thus, the scope of the claims containing the term. That is all that the law requires in this regard.

The Terms "Exendin Analog" and "Exendin Derivative"

The Examiner also asserts that claims 43-51 are indefinite based on the allegation that it is not clear what is encompassed by the recited terms, "exendin analogue" and "exendin derivative." Applicants respectfully disagree.

Initially, the Examiner repeats her assertion that the term "exendin" itself is allegedly indefinite. As discussed above, the term "exendin," as used in the present application is definite and meets the requirements of Section 112, 2nd ¶.

Additionally, and contrary to the understanding of those of skill in the art, the Examiner also asserts that the terms "analogue" and "derivative" are indefinite because they allegedly "encompass compounds that may have only as little as one molecule or one amino acid in common." This statement is not understood. It is akin to arguing, for example, that any and all organic compounds having an amine group or a carboxyl group, both of which are characteristic of proteins and peptides, are equivalent. It also proposes that any other peptide having any one of the amino acids found in exendin, e.g., a serine or an alanine, is an "analog." This is not only unsound, but unscientific because it is contrary to the understanding of those in the art. As an example, analogs are understood by those of skill in the art to be those chemical compounds that are structurally similar to another but differ in composition, such as by the replacement of one atom by an atom of a different element or in the presence of a particular functional group.² The Examiner's statement about these terms encompassing compounds that may have only one molecule or amino acid in common is contrary to common understanding.

the antagonist effects of exendin (9-39) on full length exendins. In particular, page 3, lines 30-31, clearly conveys that exendin (9-39) is not an exendin according to the invention.

² See, for example, "analogue," Merriam-Webster's Collegiate Dictionary, <http://www.m-w.com/cgi-bin/dictionary>.

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In addition to the established meanings associated therewith, the specification provides an extensive explanation of analogs and derivatives at, for example, page 17, line 1, to page 19, line 10. Therein, Applicants teach that “[e]xendin analogs or derivatives are functional variants having [a] similar amino acid sequence [to] and retaining, to some extent, at least the gastric motility- and gastric emptying-related activities of the related exendin.” Analyzing these two factors – amino acid sequence similarity and gastric motility- and gastric emptying-related activities – one of skill in the art is readily able to determine the scope of the claimed invention. Again, exemplary exendins known as of the filing date of the application, exendin-3 and exendin-4, are identified in the application along with their corresponding amino acid sequences, SEQ ID NO. 1 and SEQ ID NO. 2. Various other analogs are set forth in the specification and claims. See, e.g., SEQ ID NO. 38 and SEQ ID NO. 39. Based on these facts, as well as the teachings of the specification with respect to evaluating exendin activity, one of skill in the art is readily able to determine the scope of the claims containing the terms exendin analog and exendin derivative by evaluating whether a compound is a functional variant of an exendin, having a similar amino acid sequence to and retaining, to some extent, at least the gastric motility- and gastric emptying-related activities of the related exendin and, if so, employing the compound in the claimed method. Again, that is all that the law requires in this regard. As such, withdrawal of the rejection based on the use of the terms exendin analog and exendin derivative is respectfully requested.

The Language Related to Sequence Similarity

With respect to claims 47-50, the Examiner asserts this rejection on the allegation that the claims are “drawn to methods using exendin derivatives having various percentages of sequence similarity to sequences that are not defined.” In this regard, the Examiner inquires as to how one can determine a percentage of sequence similarity when the term “exendin” is not structurally defined.

As discussed above, exemplary exendins known as of the filing date of the application, exendin-3 and exendin-4, are identified in the application along with their corresponding amino acid sequences, SEQ ID NO. 1 and SEQ ID NO. 2. Accordingly, those of ordinary skill in the art, when analyzing an exendin derivative, are readily able to determine the amino acid sequence

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of the exendin derivative and compare it to the amino acid sequence of its associated exendin in order to determine whether the exendin derivative is within the scope of claims 47-50. That is all that the law requires in this regard. Applicants submit, therefore, that this rejection should also be withdrawn.

In conclusion, claims 31-51 particularly point out and distinctly claim the subject matter Applicants regard as the invention. It should also be noted that no reasons were provided for why claims 35-42 were included within this rejection. Applicants note that at least claims 35, 36, 41, and 42 are directed to exendin-3, exendin-4, compounds encompassed by SEQ ID NO. 38, and compounds encompassed by SEQ ID NO. 39. These exendins and exendin agonists are explicitly defined in the specification by their amino acid sequences. With respect to all claims, however, withdrawal of this rejection is requested as one of skill in the art is readily able to determine the scope of the claims.

The 35 U.S.C. §112, First Paragraph, Rejection

Claims 31-51 were rejected under 35 U.S.C. §112, first paragraph, on the allegation that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Specifically, the Examiner contends that "the specification, while being enabling for methods comprising administering exendin-3, exendin-4, the compounds encompassed by SEQ ID NO: 38, or the compounds encompassed by SEQ ID NO:39, does not reasonably provide enablement for methods comprising administering exendins, exendin agonists, exendin derivative[s], [and] exendin analogs." This rejection is respectfully traversed.

Initially, Applicants note that at least claims 35, 36, 41, and 42 are directed to exendin-3, exendin-4, compounds encompassed by SEQ ID NO. 38, and compounds encompassed by SEQ ID NO. 39. Thus, the rejection of these claims should be withdrawn in view of the Examiner's acknowledgment that they are enabled.

With regard to remaining claims, the Manual of Patent Examining Procedure (MPEP) §2164.04 requires that specific technical reasons for the Examiner's conclusion as to lack of enablement must be provided when making a rejection for alleged lack of enablement. In this

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case, the Examiner has not set forth any technical reasons for the conclusions drawn in the Office Action.

The primary basis for this rejection appears to be the Examiner's assertion that the subject matter encompassed by the terms exendin, exendin agonist, exendin analog, and exendin derivative is uncertain. The Examiner alleges that the "narrow scope of the teachings of the specification" (i.e., that exendins useful in the claimed methods are exendin-3 and exendin-4) does not support the "broad scope of the claims." The Examiner, even though she states elsewhere that it "is not clear what is encompassed" by the terms exendin, exendin analog, and exendin derivative, further alleges that the "claimed methods are broad in scope because the claims are drawn to methods using 'exendins', 'exendin agonist', 'exendin analogue' and 'exendin derivatives'." This line of reasoning is not understood.

The Examiner acknowledges that the specification demonstrates that exendin-3, exendin-4, and ¹⁴Leu, ²⁵Phe exendin-4 inhibit gastrointestinal emptying, but asserts that these compounds are not representative of the full scope of the claims. However, the Examiner has not established basis for her assertion that what Applicants teach is "narrow" with respect to the full scope of the claimed invention. Furthermore, with respect to enablement, the law makes clear that "there is no magical relation between the number of working examples and the breadth of the claims; the number and variety of examples are irrelevant if the disclosure is 'enabling' . . ." In re Borkowski, 422 F.2d 904, 910, 57 CCPA 946, 952-53, 164 USPQ 642, 646 (CCPA 1970).³

MPEP §2164.08 recites the legal principle that "the scope of enablement must only bear a 'reasonable correlation' to the scope of the claims," citing In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Given the knowledge of those of skill in the art and the teachings of the specification, which include numerous specific amino acid sequences and descriptions of known exendins and tested exendin analogs, Applicants urge that the teachings of the specification are commensurate in scope with that of the claimed invention and that the claimed methods, in which exendins, exendin agonists, exendin analogs, and exendin derivatives are recited, bear a reasonable correlation thereto. Indisputably, the specification enables practice of

³ In In re Borkowski, the claims-at-issue recited hydrocarbons that are in the vapor phase at the reaction temperature. The Court held that a representative example for the various types of hydrocarbons recited in the claims was not needed.

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the claimed method with each of exendin-3, exendin-4, and ¹⁴Leu, ²⁵Phe exendin-4. As discussed above, exendin-3 and exendin-4 were exemplary exendins known as of the filing date of the application. As further discussed above, one of skill in the art is readily able to determine compounds that are exendin agonists, including analogs and derivatives, recited in the pending method claims. The Examiner has not demonstrated that the use of other exendins or exendin agonists within the scope of these claimed methods are inoperative or would not be enabled by the specification.

The Law Does Not Require Further Functional Limitations in the Rejected Claims or That Applicants Comprehend How the Invention Works

The Examiner asserts that the teaching in the specification, specifically that exendin-3 and exendin-4 appear to bind to an exendin receptor that is different from the art-known GLP-1 receptor, cannot be extrapolated to all possible compounds that may be encompassed by the terms "exendin," "exendin agonist," "exendin analogue," or "exendin derivative." Yet, the Examiner fails to provide any technical basis for this assertion. The Examiner further remarks that the claims lack a functional limitation that would limit the scope of the methods to those methods using exendins, exendin agonists, exendin analogs, or exendin derivatives that bind to a specific "exendin" receptor that is not the GLP-1 receptor. There is no basis in the law for this purported requirement.

Further, Applicants need not teach or claim why an invention works, to be awarded a patent for their contributions. The present specification teaches that the results "indicate that the effects of exendins and exendin agonists on gastric emptying are not due [to] binding of the exendins at the cloned GLP-1 receptor, but instead that the gastric emptying effects of exendins and exendin agonists are due to their action on a separate receptor." Page 24, lines 5-10 (emphasis added). With this statement, Applicants do not wish to be bound by the hypothesized theory, nor are they required to be bound as such. In Cross v. Jizuka, the Federal Circuit reiterated "that an inventor need not comprehend the scientific principles on which the practical effectiveness of his invention rests, nor is the inventor's theory or belief as to how his invention works a necessary element in the specification to satisfy the enablement requirement of 35

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U.S.C. §112." 753 F.2d 1040, 1042 (Fed. Cir. 1985), *citing Fromson v. Advance Offset Plate, Inc.* 720 F.2d 1565, 1570, 219 USPQ 1137, 1140 (Fed. Cir. 1983).

Applicants have clearly enabled one to practice the full scope of the claimed invention and are not required to comprehend or claim how the invention works. Accordingly, Applicants respectfully submit that the teachings of the specification enable one to practice the full scope of the claimed invention, necessitating withdrawal of the present rejection.

The Examiner Misapplies the Undue Experimentation Factor, but Resolution Thereof is Unnecessary to Support Patentability of the Claimed Invention

The Examiner further asserts that: "The fact that applicant demonstrates how to evaluate gastric emptying does not enable one of skill in the art to practice the full scope of the claim[ed] invention[,] but only to test compounds." Still further, the Examiner asserts that: "The specification appears to merely provides [sic] an invitation to research to practice the full scope of the invention." The references to merely testing compounds and inviting "research" are not understood. The legally correct standard for assessing whether a specification enables the claimed invention is whether undue experimentation is required to practice the invention. See MPEP §2164.01, *citing In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976). In setting forth this rejection, the Examiner does not mention this important focus, even though the Examiner refers to the eight factors to be considered when determining that a disclosure satisfies the enablement requirement. The "determination that 'undue experimentation' would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations." MPEP §2164.01(a) (*emphasis added*); Also see, *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The Examiner, contrary to this requirement, merely lists the eight factors without elaborating on how any one of them applies to the present matter, nor discussing whether any experimentation would be "undue." Applicants submit, however, that experimentation is not the issue. The law makes it plain that Applicants' claims past muster under the patent law.

See, for example, *In re Fuetterer*, 138 USPQ 217 (CCPA 1963), which provides that it is not only proper but desirable to issue claims such as those pending in the present case. The

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claims in Fuetterer were addressed to a rubber stock for producing tire treads. The claimed rubber stock included "an inorganic salt" that was defined functionally as being "capable of holding a mixture of [a previously referred to] carbohydrate and [a previously referred to] protein in colloidal suspension in water." *Id.* at 219.

The PTO Board of Appeals affirmed a rejection of the claim as "unduly broad." According to the Board: "Since the alleged novelty appears to reside in the result desired to be obtained by the salts, it is not proper to define the salt by what it is supposed to do rather than what it does." *Id.* at 221. Judge Rich, author of the opinion in Fuetterer, promptly disposed of this rejection as unsound:

The desired result of appellant's invention is limiting the skidding of a tire tread stock on a wet surface. Appellant, in the claims before us, is not claiming this result. A myriad of alternative means for achieving this result can be easily thought of which would not require the particular combination of substances claimed by appellant. Insofar, therefore, as a "functional" claim may mean one which covers all means of arriving at the desired result, although the means by which such result is obtained is entirely different from that disclosed by the applicant, it is apparent that appellant's claims are not "functional."

Id. at 221 (emphasis added). Similarly, the result to be achieved by the use of the invention claimed here relates to either reducing gastric motility or delaying gastric emptying in a subject. There are plainly other means for reducing gastric motility or delaying gastric emptying in a subject (e.g., by the use of an amylin or an amylin agonist) that do not require the particular means claimed by Applicants.

In Fuetterer, Judge Rich also stressed that patent applicants must be able to obtain claims that adequately protect their inventions, even if experimentation may be required to determine if a product or method falls within the scope of the claim. Judge Rich described Fuetterer's claim and the rejection as follows:

The rejection of the claims for "undue breadth" places particular emphasis on (1) an alleged "undue burden upon the public to determine what salts are suitable for obtaining the desired results" (emphasis ours), and (2) an alleged "undue [amount of] experimentation" required of those skilled in the art to determine those salts possessing the "function asserted" by the instant claims.

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The undue breadth rejection phase of the instant case appears in the following posture. Appellant has described his invention as comprehending the use therein of any inorganic salt capable of performing a specific function in a specific combination and he has disclosed specifically four such salts which are capable of performing this function. The examiner and the board, believing that not all inorganic salts are capable of performing this function and that one skilled in the art would not know offhand which inorganic salts are capable of so functioning, have rejected the claims as "unduly broad."

Id. at 222-223. According to Judge Rich, however, this was all "beside the point" and could not support the rejection:

We find the arguments of the board and the examiner relating to experimentation necessary to determine the suitability of undisclosed salts to operate in appellant's claimed combination beside the point. Appellant's invention is the combination claimed and not the discovery that certain inorganic salts have colloid suspending properties. We see nothing in patent law which requires appellant to discover which of all those salts have such properties and which will function properly in his combination. The invention description clearly indicates that any inorganic salt which has such properties is usable in his combination.

Id. at 223 (emphasis added). Likewise, Applicants' invention in this case is not the discovery that certain compounds have exendin or exendin agonist activity, but rather that such compounds are useful in reducing gastric motility or delaying gastric emptying in a subject.

Judge Rich further emphasized that an Applicants' claims may not be restricted so that they are easily avoided simply by identifying an undisclosed compound that will work:

If others in the future discover what inorganic salts additional to those enumerated do have such properties, it is clear appellant will have no control over them per se, and equally clear his claims should not be so restricted that they can be avoided merely by using some inorganic salt not named by appellant in his disclosure. The only "undue burden" which is apparent to us in the instant case is that which the Patent Office has attempted to place on the appellant.

Id. (emphasis added). Similarly, if others in the future discover other exendins or exendin agonists aside from those set out in Applicants' specification with the ability to reduce gastric

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motility or delay gastric emptying in a subject, Applicants will have no control over them per se.

Further limitation of the claims is not sanctioned under the law. In In re Johnson and Farnham, 194 USPQ 187, 195 (CCPA 1977), the court reversed a rejection of claims, emphasizing that:

As we said in In re Goffe, 542 F.2d 564, 567, 191 USPQ 429, 431 (CCPA 1976): “[T]o provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for ‘preferred’ materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts. See In re Fuetterer, 50 CCPA 1453, 1462, 319 F.2d 259, 265, 138 USPQ 217, 223 (1963).

Further, following Fuetterer, it is plain that, under the law, Applicants' claims cannot be so restricted by the Patent Office that they can be avoided merely by using some compound not explicitly named in the disclosure.

For this further reason, Applicants submit that all pending claims are properly enabled, that the rejection is, therefore, improper and should be reversed.

Claims 43-46

Applicants also note that Examiner focuses on claims 43-46 and their recitation of exendin analogs or exendin derivatives having an activity that is based on the exendin of which it is an analog or derivative. The Examiner alleges that these particular claims are not enabled “because exendins may have multiple ‘activities’ and because the specification only teaches one activity for a limited number of examples.” Applicants respectfully disagree and submit that the Examiner’s assertion that exendins may have multiple activities is not relevant to the present issue. The present issue is solely whether the specification enables one skilled in the art to practice the claimed invention, which is directed toward one activity of exendins – regulating gastrointestinal motility. It does so and no further examples are required to accomplish the same.

The specification clearly enables one of skill in the art to determine exendin activity as contemplated in claims 43-46. For example, the specification teaches how the activity of an exendin agonist can be determined at page 13, line 4, to page 14, line 5. Therein, Applicants teach that the effects of exendins or exendin agonists on gastric motility and gastric emptying

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can be identified, evaluated, or screened for, using the methods described in Examples 1-3 or other art-known or equivalent methods for determining gastric motility. In that regard, Applicants teach the use of negative receptor assays or screens for the evaluation and/or confirmation of exendin agonist activity. Further, Applicants teach that a method for use in identifying or evaluating the ability of a compound to slow gastric motility comprises: (a) bringing together a test sample and a test system, said test sample comprising one or more test compounds, said test system comprising a system for evaluating gastric motility, said system being characterized in that it exhibits, for example, elevated plasma glucose in response to the introduction to said system of glucose or a meal; and, (b) determining the presence or amount of a rise in plasma glucose in said system. With such teachings, as well as the knowledge possessed by one of skill in the art, one is clearly able to practice the invention of claims 43-46.

Claims 47-50

Applicants note that the Examiner also focuses on claims 47-50 and their recitation of exendin analogs or exendin derivatives having an amino acid sequence similarity that is based on the exendin of which it is an analog or derivative. The Examiner asserts that these particular claims are not enabled "because the specification fails to teach how to make the exendin analogues or derivatives as claimed." The Examiner's attention is directed toward, for example, page 17, line 1, to page 19, line 10, where Applicants teach how to make exendin analogs and derivatives of the invention. With such teachings, as well as the knowledge possessed by one of skill in the art, one is clearly able to practice the invention of claims 47-50.

In conclusion, this rejection should be withdrawn. The specification clearly enables the full scope of claims 31-51, contrary to the Examiner's conclusion.

The 35 U.S.C. §102(b) Rejection

Claims 33-34 and 43 were rejected under 35 U.S.C. §102(b) as being allegedly anticipated by Dupre et al. (Dupre, J. et al., Diabetes, 44:626-30 (1995)) as allegedly evidenced by either Goke et al. (Goke, R. et al., J. Biol. Chem., 268(26):19650-55 (1993)) or Rai et al. (Rai, A. et al., Am. J. Physiol., 265:G118-G125 (1993)). This rejection is respectfully traversed.

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The Examiner's rejection is based on the assertion that a derivative may be a compound that comprises only one amino acid of an "exendin." Based on this, the Examiner incorrectly concludes that "the teachings of the prior art meet the limitations of the claims." Dupre et al. teaches that GLP-1[7-36] retards gastric emptying of food in normal humans. As noted in Applicants' Response filed July 27, 2001, however, exendin agonists do not include GLP-1. Additionally, as defined in the specification, GLP-1 is not an exendin analog or an exendin derivative, as it is not a functional variant of an exendin, which functional variants retain, to some extent, at least the gastric motility- and gastric emptying-related activities of the related exendin. Thus, this rejection must be withdrawn because the cited references do not teach each and every element of Applicants' claimed invention.

The 35 U.S.C. § 103(a) Rejection

Claims 31-34 and 37-39 were rejected under 35 U.S.C. §103(a) as allegedly being obvious over Dupre et al. (Dupre, J. et al., *Diabetes*, 44:626-30 (1995)) in view of either Chernish et al. (U.S. Patent No. 3,862,301) or Kolterman et al. (PCT Publication No. WO 95/07098) and further in view of Eng (U.S. Patent No. 5,424, 286). This rejection is respectfully traversed.

Similar to the Examiner's 35 U.S.C. §102(b) rejection, the Examiner's argument rests on the assertion that GLP-1[7-36], taught by Dupre et al. to be useful in treating diabetes, is an exendin analog or exendin derivative according to the presently claimed invention. Again, exendin agonists, exendin derivatives, and exendin analogs according to the present invention do not include GLP-1. Thus, this rejection must be withdrawn because the cited references do not teach or suggest each and every element of Applicants' claimed invention.

Conclusion

Applicants again submit that the pending claims are in condition for allowance. Notification to that effect is respectfully requested. Should the Examiner have any remaining questions, the Examiner is encouraged to contact Applicants' undersigned Representative for prompt resolution thereof.

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Respectfully submitted,

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